PACKAGE LEAFLET: INFORMATION FOR THE USER

Pabrinex® Intravenous High Potency, Solution for injection
(Vitamins B & C Injection)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. WHAT PABRINEX INTRAVENOUS INJECTION IS AND WHAT IT IS USED FOR

Vitamins B and C are important for a number of bodily functions including releasing energy from food and in the formation of healthy skin, bones and teeth.

Pabrinex Intravenous High Potency, Solution for injection ('Pabrinex') provides additional vitamins B and C to correct deficiencies that may have occurred, for example:
- in alcoholism
- after infections
- after operations
- in certain psychiatric states.

The product is also used to maintain levels of vitamins B and C in patients who are on long-term intermittent haemodialysis.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN PABRINEX INTRAVENOUS INJECTION

You MUST NOT be given Pabrinex Intravenous injection:
- if you are allergic to any of the ingredients of this medicine *(listed in section 6)*
- if you have a history of sensitivity to vitamins B and/or C.

Warnings and precautions
Talk to your doctor before taking Pabrinex Intravenous injection. Pabrinex Intravenous injection should be given with extreme caution if you have:
- ever had a mild allergic reaction (sneezing or mild asthma) to any previous injections of vitamin B1 (thiamine). This could mean that you may have become hypersensitive, and could have a more **severe allergic reaction** if given Pabrinex Intravenous injection.

Other medicines and Pabrinex Intravenous injection
Tell your doctor if you are taking, have recently taken, or might take, any other medicines.
- Levodopa (used in the treatment of Parkinson's disease) - Pabrinex interferes with the effects of this medicine.
- Vitamin B1 (thiamine) injections - if you are on repeated injections of such preparations, Pabrinex Intravenous injection may cause sneezing or mild asthma (chest tightness and wheezing) or even anaphylactic shock if you have become hypersensitive.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant, planning to become pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Driving and using machines
Pabrinex is not expected to affect your ability to drive or operate machinery.

Pabrinex contains sodium:
This medicinal product contains approximately 3.4 mmol (or 79 mg) sodium per dose (**1 pair of 5ml ampoules**). To be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains approximately 6.8 mmol (or 158mg) sodium per dose (**1 pair of 10ml ampoules**). To be taken into consideration by patients on a controlled sodium diet.

3. HOW PABRINEX INTRAVENOUS INJECTION IS GIVEN

Pabrinex Intravenous injection will be given to you by a healthcare professional by drip infusion into a vein. The product comes in two ampoules, the contents of which are first diluted with either saline or 5% glucose solution and then given over a period of 30 minutes.

This medicine is for injection into a vein only and should not be given by any other route.

Dosage for adults including the elderly:
- *For rapid therapy of severe depletion or malabsorption of water soluble vitamins B and C, particularly in alcoholism:* 2 to 3 pairs of 5ml ampoules (1 pair = ampoule 1 + ampoule 2) diluted with 50ml to 100ml of infusion solution and injected over 30 minutes at intervals decided by your doctor (typically every 8 hours).
- *For psychosis following unconsciousness from a narcotic drug (narcosis) or electroconvulsive therapy, or poisoning from infection:* 10ml of the mixed ampoules (1 pair) diluted with 50ml to 100ml of infusion solution and injected over 30 minutes. Injected twice daily for up to 7 days.
- *For haemodialysis patients:* 10ml of the mixed ampoules (1 pair) diluted with 50ml to 100ml of infusion solution and injected over 30 minutes. Injected at the end of dialysis, once every 2 weeks.

Use in children and adolescents:
Pabrinex Intravenous injection is not usually given to children; however, suitable doses according to the child's age are:

Age	Dose
under 6 years	1/4 of the adult dose
6-10 years	1/3 of the adult dose
10-14 years	1/2 to 2/3 of the adult dose
14 years and older	one adult dose

The exact dose you will be given will be decided by your doctor who will monitor your condition and determine what treatment you need. If you feel that you have been given an inappropriate dose or if you would like more information about Pabrinex Intravenous injection, speak to your doctor.

If you are given more Pabrinex Intravenous injection than you should
This product will be given to you under medical supervision. It is therefore unlikely that you will be given too much. However, if you feel unwell, you should tell your doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- **Allergic reaction -** if following your injection you experience symptoms such as sneezing or mild asthma (chest tightness and wheezing) **tell your doctor immediately**. This may be an indication that you are sensitive to Pabrinex Intravenous injection and should not be given a repeat dose.
- Severe allergic reaction (anaphylactic shock) - may result from repeated injections of this medicine. Symptoms may include: swelling of the face and or throat, rash, severe itching, difficulty in breathing and loss of consciousness due to very low blood pressure.
- Low blood pressure and feeling of 'pins and needles' (mild paraesthesia) can occur in some patients.
- Mild ache at the site of the injection - some swelling may develop at the site of injection.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PABRINEX INTRAVENOUS INJECTION

Keep this medicine out of the sight and reach of children.

Pabrinex should be stored below 25°C but not frozen, and protected from light.

Once diluted in an infusion fluid Pabrinex should normally be used immediately.

If necessary the diluted product can be kept at room temperature:

For 7 hours in the following infusion fluids:

- Glucose 5%
- Physiological saline (sodium chloride 0.9%)
- Sodium lactate M/6;

For 4 hours in the following infusion fluids:

- Glucose 4.3% with sodium chloride 0.18%
- Glucose 5% with potassium chloride 0.3%

Do not freeze diluted solution.

Do not use this medicine after the expiry date which is stated on the outer carton and ampoule labels after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pabrinex Intravenous injection contains
The **active** ingredients are:

AMPOULE 1	**5ml**	**10ml**
thiamine hydrochloride (vitamin B1)	250mg	500mg
riboflavin (vitamin B2)	4mg	8mg
pyridoxine hydrochloride (vitamin B6)	50mg	100mg
AMPOULE 2		
ascorbic acid (vitamin C)	500mg	1000mg
nicotinamide	160mg	320mg
glucose (as monohydrate)	1000mg	2000mg

The **other ingredients** are: edetic acid, sodium hydroxide and water for injections.

What Pabrinex Intravenous injection looks like and contents of the pack
The product is supplied in pairs of amber coloured glass ampoules containing 5ml or 10ml of sterile solution. Each pack contains 6 or 10 pairs of 5ml ampoules or 5 pairs of 10ml ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Kyowa Kirin Limited
Galabank Business Park
Galashiels
TD1 1QH
United Kingdom.

Manufacturer
Haupt Pharma Wülfing GmbH
Bethelner Landstraße 18
D-31028 Gronau/Leine
Germany.

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Warnings and precautions
Talk to your doctor before taking Pabrinex Intravenous injection.

Pabrinex Intravenous injection should be given with extreme caution if you have:
- ever had a mild allergic reaction (sneezing or mild asthma) to any previous injections of vitamin B1 (thiamine). This could mean that you may have become hypersensitive, and could have a more **severe allergic reaction** if given Pabrinex Intravenous injection.

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Marketing Authorisation Holder
Kyowa Kirin Limited
Galabank Business Park
Galashiels
TD1 1QH
United Kingdom.

Manufacturer
Haupt Pharma Wülfing GmbH
Bethelner Landstraße 18
D-31028 Gronau/Leine
Germany.

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